DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Olympus Medical Systems Corporation
% Ms. Laura Storms-Tyler
Olympus America, Inc.
3500 Corporate Parkway, PO Box 610
Center Valley, PA 18034-0610

JUL 27 2015

Re: K063683
Trade/Device Name: XEU-M60A Endoscopic Ultrasound Center
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX and ODG
Dated (Date on orig SE ltr): December 5, 2006
Received (Date on orig SE ltr): December 14, 2006

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of February 8, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.3.1 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

XEU-M60A ENDOSCOPIC ULTRASOUND CENTER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N				N		Note 2
	Trans-vaginal							
	Trans-urethral	N				N		Note 2
	Trans-esoph. (non-Card.)	N				N		Note 2
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N				N		Note 2
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Specification for "Other" :
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.
Intraluminal ultrasound for upper airways and tracheobronchial tree

Note 2: 3-D Imaging

David A. Jayson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063683

4.3.2 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

UM-2R / 3R ULTRASONIC PROBES

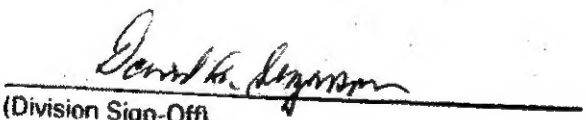
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N						
	Trans-vaginal							
	Trans-urethral	N						
	Trans-esoph. (non-Card.)	N						
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA ; E= added under Appendix E

Additional Comments:

Note 1: Specification for "Other" :
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.
Intraluminal ultrasound for upper airways and tracheobronchial tree



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4.3.3 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

UM-DP12/20-25R ULTRASONIC PROBES

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N						
	Trans-vaginal							
	Trans-urethral	N						
	Trans-esoph. (non-Card.)	N						
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Specification for "Other" :
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.
Intraluminal ultrasound for upper airways and tracheobronchial tree

David B. Seymour

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063683

4.3.4 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

ULTRASONIC GASTROVIDEOSCOPE GF TYPE UM130

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N						
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note1: Specification for "Other"
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.

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and Radiological Devices
510(k) Number K063683

4.3.5 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

EUS EXERA ULTRASONIC GASTROVIDEOSCOPE OLYMPUS GF TYPE UM160

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N						
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.

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and Radiological Devices
510(k) Number K063683

4.3.6 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

ULTRASONIC GASTROVIDEOSCOPE OLYMPUS XGF TYPE UM180

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

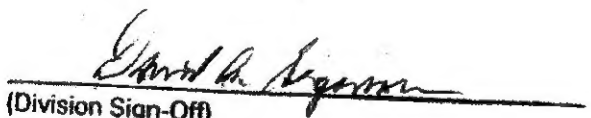
Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N						
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.



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510(k) Number K063683

4.3.7 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

GF-UE160-AL5 ULTRASONIC GASTROVIDEOSCOPE

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N				N		
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N				N		
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.) (Note 1)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Note1: Specification for "Other"
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.

David A. Lagzdins

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063683

4.3.9 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

GF-UCT140-AL5 ULTRASONIC GASTROVIDEOSCOPE

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N				N		
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N				N		
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Note1: Specification for "Other"
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.

David A. Seguson

(Division Sign-Off)
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and Radiological Devices
510(k) Number K063683

4.3.8 DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

GF-UC140P-AL5 ULTRASONIC GASTROVIDEOSCOPE

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (specify)							
	Intraoperative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N				N		
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 1)	N				N		
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Note1: Specification for "Other"
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063683

K063683

510(k) SUMMARY

FEB 8 2007

December X, 2006

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo,
Japan 192-8507
Establishment Registration No: 8010047

- Official Correspondent:

Laura Storms-Tyler
Executive Director
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-5688
FAX: 484-896-7128
Email:Laura.storms-tyler@olympus.com
Establishment Registration No: 2429304

- Manufacturer:

OLYMPUS MEDICAL SYSTEMS CORP.
HINODE PLANT
34-3 Hirai Hinode-Machi, Nishitama-gun, Tokyo
Japan, 190-0182
Establishment Registration No:8010047

2 Device Identification

- Device Trade Name:

Model Name	Device Name
XEU-M60A	ENDOSCOPIC ULTRASOUND CENTER
UM-2R/3R	ULTRASONIC PROBES
UM-DP12/20-25R	ULTRASONIC PROBES
GF-UM130	ULTRASONIC GASTROVIDEOSCOPE
GF-UM160	EUS EXERA ULTRASONIC GASTROVIDEOSCOPE
XGF-UM180	ULTRASONIC GASTROVIDEOSCOPE
GF-UE160-AL5	ULTRASONIC GASTROVIDEOSCOPE
GF-UC140P-AL5	ULTRASONIC GASTROVIDEOSCOPE
GF-UCT140-AL5	ULTRASONIC GASTROVIDEOSCOPE

- Common Name: Diagnostic Ultrasound System

- Regulation Number:

892.1550 Ultrasound Pulsed Doppler Imaging System
892.1560 Ultrasonic Pulsed Echo Imaging System
892.1570 Diagnostic Ultrasound Transducer
876.1500 Endoscope and Accessories

- Regulatory Class: II

■ Product Code: 90-IYN/90-IYO/90-ITX/78-KOG

3 Predicate Device Information

■ Ultrasound System

Subject device	Predicate device	
	Name	Control number
XEU-M60A ENDOSCOPIC ULTRASOUND CENTER	EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER	K043275
	EU-C60 EUS EXERA COMPACT ENDOSCOPIC ULTRASOUND CENTER	K010591

■ Ultrasonic Gastrovideoscopes and Probes

Subject device	Predicate device	
	Name	Control number
UM-2R/3R ULTRASONIC PROBES	UM-2R/3R ULTRASONIC PROBES	K944610 K982323 K982610
UM-DP12/20-25R ULTRASONIC PROBES	UM-2R/3R ULTRASONIC PROBES	Based upon K944610, K982323, K982610, Olympus determined that no 510(k) was required for device changes.
GF-UM130 ULTRASONIC GASTROVIDEOSCOPE	GF-UM130 ULTRASONIC GASTROVIDEOSCOPE	K971660 K011886
GF-UM160 EUS EXERA ULTRASONIC GASTROVIDEOSCOPE	GF-UM160 EUS EXERA ULTRASONIC GASTROVIDEOSCOPE	K011886
XGF-UM180 ULTRASONIC GASTROVIDEOSCOPE	GF-UM160 ULTRASONIC GASTROVIDEOSCOPE	This submission
GF-UE160-AL5 ULTRASONIC GASTROVIDEOSCOPE	GF-UE160-AL5 ULTRASONIC GASTROVIDEOSCOPE	K051541
GF-UC140P-AL5 ULTRASONIC GASTROVIDEOSCOPE	GF-UC140P-AL5 ULTRASONIC GASTROVIDEOSCOPE	K011314
GF-UCT140-AL5 ULTRASONIC GASTROVIDEOSCOPE	GF-UCT140-AL5 ULTRASONIC GASTROVIDEOSCOPE	K012080

4 Device Description

The combination of the XEU-M60A Endoscopic Ultrasound Center, UM-2R/3R Ultrasonic Probes, UM-DP12/20-25R Ultrasonic Probes, GF-UM130 Ultrasonic Gastrovideoscope, GF-UM160 Ultrasonic Gastrovideoscope, XGF-UM180 Ultrasonic Gastrovideoscope, GF-UE160-AL5 Ultrasonic Gastrovideoscope, GF-UC140P-AL5 Ultrasonic Gastrovideoscope, and GF-UCT140-AL5 Ultrasonic Gastrovideoscope enables the acquisition and display of high-resolution and high-penetration, real-time ultrasound B-mode endoscopic images.

5 Indications for Use

The indications for use for the XEU-M60A Endoscopic Ultrasound Center are as follows:

- Transrectal
- Transurethral
- Transesophageal(non-cardiac)
- Gastrointestinal tract, biliary, pancreatic duct and surrounding organs
- Intraluminal ultrasound for upper airways and tracheobronchial tree
- 3-D Imaging

6 Comparison of Technological Characteristics

The XEU-M60A Endoscopic Ultrasound Center operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis.

Technological Characteristics of this device is identical to the predicate devices identified in item 3.